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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/887,569	06/25/2001	Maurice M. Moloney	9369-183	8071

7590

01/07/2005

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EXAMINER

FOX, DAVID T

ART UNIT

PAPER NUMBER

1638

DATE MAILED: 01/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/887,569

Applicant(s)

MOLONEY ET AL.

Examiner

David T. Fox

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 October 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17,20,23-25 and 30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17,20,23-25 and 30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 17, 20 and 23-24 remain rejected under 35 U.S.C. 102(b) as being anticipated by WO 91/13993 (UPJOHN), as stated on page 2 of the last Office action.

Claims 17, 20 and 23-25 remain rejected under 35 U.S.C. 103(a) as being unpatentable over WO 91/13993 (UPJOHN) in view of Vandekerckhove et al, as stated on page 2 of the last Office action.

Claim 30 remains rejected under 35 U.S.C. 103(a) as being unpatentable over WO 91/13993 (UPJOHN) in view of Vandekerckhove et al as applied to claims 17, 20 and 23-25 above, and further in view of Orlikowska et al, as stated on pages 2-3 of the last Office action.

No claim is allowed.

Applicant's arguments filed 27 October 2004 have been fully considered but they are not persuasive.

Applicant urges that the anticipation rejection is improper, since UPJOHN teaches the cleavage of a portion of the signal peptide from the fusion protein, so that the reference fails to teach the "accumulation" of a "fusion protein" comprising the entire signal peptide linked to somatotropin. The Examiner notes that UPJOHN teaches that at least two to four amino acids from the plant peptide will remain linked to the non-plant somatotropin peptide (see, e.g., page 20 of UPJOHN, lines 14-16). Thus the reference indeed teaches a "fusion protein" comprising somatotropin fused to non-somatotropin amino acid residues, as instantly claimed.

Applicant urges that the obviousness rejections are improper, since UPJOHN teaches away from a fusion protein, so that there is no motivation to combine the references. The Examiner maintains that UPJOHN do indeed teach a fusion protein, as stated above, and also teach the desirability of using plants as bioreactors to produce pharmaceutical proteins such as somatotropin, as stated in the last Office action. Furthermore, Vandekerckhove et al teach the advantages of producing pharmaceutical peptides as fusion proteins with highly accumulated seed storage proteins, as stated in the last Office action, and broadly suggest the application of their technique with any peptide of interest, as stated in the last Office action (see, e.g., page 929, column 1, second paragraph and column 2, second paragraph; page 931, column 2, first and second full paragraphs). Thus, motivation to combine the references is explicit.

Furthermore, Applicant's single example of success depends upon the use of an oil body protein-encoding nucleotide sequence to produce a fusion protein comprising an oil body protein, wherein said fusion protein stably accumulates in the seed in large quantities. In contrast, the claims are broadly drawn to the use of any fusion protein-encoding nucleotide sequence encoding any fusion protein.

See *In re Lindner*, 173 USPQ 356 (CCPA 1972) and *In re Grasselli*, 218 USPQ 769 (Fed. Cir. 1983) which teach that the evidence of nonobviousness should be commensurate with the scope of the claims.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Fox whose telephone number is 571-272-0795. The examiner can normally be reached on Monday through Friday from 10:30AM to 7:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy J. Nelson, Ph.D., can be reached on 571-272-0804. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

January 3, 2005

DAVID T. FOX
PRIMARY EXAMINER
GROUP 180-1638

